REMARKS

Claims 25 and 69-86 are currently pending. Claims 25 and 69-86 have been rejected. The specification has been objected to allegedly for the introduction of new matter. Claims 25 and 69-86 and the specification are hereby submitted for review and consideration.

Summary of the June 23, 2003 Interview

Applicant's Attorney met with Examiner Choi to discuss proposed claims on June 23, 2003. During that interview the Examiner discussed support for a claim which recited a protein to carbohydrate weight ratio of "about 7 to 1" as well as "about 20 g protein" and "about 3 g carbohydrate".

In the Office Action issued on October 3, 2003, Examiner Choi has now requested that the Applicants set forth, for the record, the reasons that the amendments to the specification do not constitute new matter, and the reasons that the amended claims meet the requirements for written description and are definite.

Objection to the Specification for New Matter under 35 U.S.C. § 132

The specification as Amended in the response of June 27, 2003 stands objected to because allegedly the Amendment to the specification introduces new matter. The Examiner has maintained the term "about" constitutes new matter because allegedly the original disclosure did not indicate that the amounts in Example 1 could be approximate. In support of his objection the Examiner has relied on *Ex parte Bauer and Glabe,* 72 USPQ 6, (Bd. Pat. App. & Int. 1946) and requested that the Applicants distinguish the present application from *Bauer.*[1]

[1] The Examiner also cited and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2D 1016 (CAFC 1991). *Amgen* deals with indefiniteness of a claim term rather than new matter. Thus our comments do not address *Amgen* in regard to the new mater rejection.

The Amendment to the specification is presented below.

> The present invention provides a method for supplementing the diet of an athlete, comprising administering as part of the diet an effective amount of a supplement comprising an effective amount of L-arginine, a source of amino acids and an effective amount of at least one substance which increases ntiric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, glucomannan and folic acid, **wherein the source of amino acids is a protein and the composition further comprises a carbohydrate, wherein the weight ratio of protein to carbohydrate is about 7 to 1.**
>
> The present invention further provides a method for supplementing the diet of a human comprising administering immediately after an exercise period about 28 grams of a dietary supplement comprising an effective amount of L-arginine, **about 20 grams of protein, about 3 grams of carbohydrate** and an effective amount of at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, glucomannan, and folic acid."

(*Emphasis added.*)

Thus the disputed amendments to the specification are a "protein to carbohydrate weight ratio of about 7 to 1" as well as "about 20 grams of protein, about 3 grams of carbohydrate".

Applicants believe that one of skill in the art would understand that the Application as filed clearly has support for the amendments because the specification in fact expressly discloses the terms "about 7 to 1", "about 20 g of protein" and "about 3 g of carbohydrate". *See* Example 1, at page 10, lines 10-19 which discloses a scoop of approximately 28 grams comprising 20 g of protein and 3 grams of carbohydrate; Example 2 at page 12, lines 3-6 which discloses 2 scoops of approximately 56 grams comprising 40 g of protein and 6 grams of carbohydrate; and the description of the invention at page 9, line 15-30, which discloses the preferred methods for supplementing the diet of an athlete wherein from about 0.5 to about 10 scoops are

administered on a daily basis, wherein the dosage is preferable administered 3 times a day.

Applicants believe that one of skill in the art would understand that a serving of 1 scoop of approximately 28 grams would comprise about 20 grams of protein and about 3 grams of carbohydrate (not a precise amount). Thus the Applicants believe that the term "about" does not constitute new matter because one of skill in the art would have understood the specification as providing support for the term "about". Moreover, Applicants also believe that the disclosure in the description and Examples that multiple scoops and fractions of scoops could be administered also supports the term "about". *See* page 9, lines 15-30.

The Applicants also believe that the term "about 7 to 1" has support in the description because the weight ratio of about 7 to 1 describes the ratio of protein to carbohydrate over the entire range of daily dosages wherein the daily dosage ranges from about 0.5 scoops to about 10 scoops. Thus, one of skill in the art would understand that Example 1 discloses administering a single scoop of approximately 28 g of a supplement which has about 20 grams of protein, and about 3 grams of carbohydrate, wherein the weight ratio of protein to carbohydrate is about 7 to 1. *See* page 10, lines 10-19. Likewise, one of skill in the art would understand that the description discloses administering a half a scoop of supplement comprising about 14 grams of supplement which has about 10 grams of protein and about 1.5 grams of carbohydrate, wherein the protein to carbohydrate weight ratio is about 7 to 1. *See* page 9, lines 15-30.

Applicants do not believe *Bauer* provides a basis for a new matter rejection. In *Bauer,* the appealed claims related to methods of preserving milk or milk products by

adding a proportion of an alkali acetate salt to the milk or milk product. The claims were rejected on the ground of new matter over the expression "containing **predominantly**" (emphasis added). The court found that the term "predominantly" meant in any amount greater than 50% and that the original specification did not disclose any ratio of ingredients in that range. Rather, the court found that the only amount disclosed by the specification was an amount greater than 2%. Thus, the court found there was no support for claiming the 25-fold increase in acetate salt embraced by the claim term predominantly. *See Bauer.*

The present application is clearly distinguishable from *Bauer*. In the present case the protein to carbohydrate weight ratio of "about 7 to 1" was derived from and is completely consistent with Examples 1 and 2 as well as the description. For instance, one of skill in the art would understand that the term "about 7 to 1" accurately describes the weight ratio of protein of Example 1 because Example 1 comprises about 20 grams of protein and about 3 grams of carbohydrate. Moreover, one of skill in the art would understand that the term "about" is being used in its ordinary and customary usage to mean "almost" or "approximately. See MPEP 2163.07, "[t]he mere inclusion of dictionary or art recognized definitions known at the time of filing an application would not be considered new matter."

Thus, Applicants believe that the Amendment to the specification reciting the carbohydrate to protein weight ratio of "about 7 to 1", as well as the term "about 20 grams of protein, about 3 grams of carbohydrate" has support in the original specification and does not represent new matter.

Claim Rejections under 35 U.S.C. § 112 for Lack of Written Description

The Examiner has rejected claims 25 and 68-86 under 35 U.S.C. § 112 first paragraph, for allegedly failing to comply with the written description requirement. The Examiner has alleged that the claims contain subject matter, which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time of the application had possession of the invention. The Examiner has stated that the use of the term "about" other than for 28 grams appears to constitute new matter. Examiner has alleged that the term "about" is new because Example 1 did not indicate that the amounts were approximate. In making his rejection the Examiner has asked the Applicants to distinguish the present application from *Bauer*.

Applicants believe that the present claims are clearly distinguishable from the situation in *Bauer*. In *Bauer*, the claims were amended to recite an increase in the proportion of acetate salt wherein the increase in acetate salt was not even remotely described in the original specification. *See supra*. In contrast, in the present case the claims were amended to recite a protein and carbohydrate ratio of "about 7 to 1" which was derived from Examples 1 and 2, as well as the description of the range of daily dosages. *See supra*. There is support in the original specification because *inter alia*, one of skill in the art would have understood that the supplement in Example 1, in fact, comprises about 20 grams of protein and the about 3 grams of carbohydrate in a ratio of about 7 to 1.

Applicants believe that the claims satisfy the test for compliance with the written description requirement of § 112 because the description clearly allows persons of ordinary skill in the art to recognize that the Applicants invented what is claimed and that the Applicants were in possession of the invention when they filed the Application.

See Moba v. Diamond Automation, 325 F.3d 1306, 1321; 66 U.S.P.Q.2d (BNA) 1429 (*Fed. Cir.* 2003).

Applicants believe that the claims satisfy the written description requirement and are readily distinguishable from *Bauer*. Thus, Applicants request that the rejection for lack of written description be withdrawn.

Claim Rejections under 35 U.S.C. § 112 for Indefiniteness

The Examiner has also rejected the claims for indefiniteness under 35 U.S.C. 112 because allegedly the claim term "about 7 to 1" in claims 25,68-86; "about 20 grams" and "about 3 grams" in claims 68 and 78; and "about 1.5 grams" in claims 69 are relative terms which render the claims indefinite. In making his rejection the Examiner has asked the Applicants to distinguish the present claims from *Bauer* and *Amgen.*

As a preliminary matter, Applicants believe the claims of the present Application are readily distinguishable from *Bauer* because one of skill in the art would understand that the present claims are derived from a protein to carbohydrate weight ratio explicitly and implicity disclosed in the specification as filed. *See supra*.

Moreover, in *Amgen*, the term "about" was held to be indefinite because there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity was covered by the term "about". Thus, the Federal Circuit found that a limitation of "at least about 160,000" was indefinite because there was no way to accurately measure the specific activity of a protein. The court based its opinion on the fact that a bioassay provided an imprecise form of measurement with a large range of error. The term "about 160,000 IU/AU, coupled with the range of error failed to distinguish the claims over the prior art

or to permit one to know what specific values below 160,000, if any might constitute infringement.

> The district court found that "bioassays provide an imprecise form of measurement with a range of error" and that use of the term "about" 160,000 IU/AU, coupled with the range of error already inherent in the specific activity limitation, served neither to distinguish the invention over the close prior art (which described preparations of 120,000 IU/AU), nor to permit one to know what specific activity values below 160,000, if any, might constitute infringement.

See Amgen at 1017.

> When the meaning of claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid.

See Id.

Applicants believe that the present situation is readily distinguishable from *Amgen* because one of skill in the art could readily determine a protein to carbohydrate weight ratio of "about 7 to 1" as well as determine "about 20 grams", "about 3 grams," using an ordinary scale. Moreover, Applicants believe that based on the specification one of skill would understand that the claim term "about" was being used in its ordinary meaning to mean "almost" or "approximately".

Thus, Applicants believe that the claims are definite and request that the rejection for indefiniteness be withdrawn.

CONCLUSION

The courtesies and assistance extended by Examiner Choi to applicant's undersigned attorney are gratefully acknowledged and appreciated.

Applicants believe that this Application is now in condition for allowance and such action is respectfully requested. If for any reason the Examiner believes that contact with the Applicant's attorney would advance the prosecution of this application, he is invited to contact the undersigned at the number given below.

Respectfully Submitted,

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